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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,934	02/15/2002	Richard M. O'Hara JR.	WYS-00701	3689

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EXAMINER	
OUSPENSKI, ILIA I	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/076,934	O'HARA ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9-12 and 28-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9-12 and 28-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment/remarks, filed on 01/25/2007, are acknowledged.

Claims 5 – 8 and 13 – 27 have been cancelled.

Claims 32 – 37 have been added.

Claims 1 – 4, 9 – 12, and 28 – 37 are pending.

2. This Office Action will be in response to Applicant's amendment and arguments, filed on 01/25/2007.

The rejections of record can be found in the previous Office Action, mailed on 07/25/2006.

3. The rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29 and 31 stand rejected, and newly added claim 37 is rejected, under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention.

The specification does not provide a sufficient enabling description of the claimed methods, because Applicant has not met the conditions that the PV1 antibody, which is required to practice the claimed invention, be known and readily available to the public or obtainable by a repeatable method set forth in the specification.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that one skilled in the art at the time of filing of the instant application, with the information disclosed in the present application, would be able to make and use the PV1 antibody, and that the PV1 hybridoma was deposited with the ATCC and has been assigned ATCC accession no. HB-12352.

In response, the guidance provided in the specification, and the skill in the art, may enable a skilled artisan to produce an anti-CD28 antibody, and a corresponding scFv molecule; however, the molecule so obtained will not be the instantly recited RV1, because, as one of skill in the art is aware, each antibody is unique.

Further, biological materials must be known and readily available to the public (See MPEP 2404.01). Neither concept alone is sufficient. The fact that the PV1 hybridoma has been deposited with the ATCC does not establish that upon issuance of a patent on this application such material would continue to be accessible to the public. The applicant did not make of record any of the facts and circumstances surrounding the access to the biological materials, and there is no assurance that the depository allows unlimited access to the material, nor that the deposit will be maintained for the

enforceable life of the patent. In the absence of objective evidence that the PV1 molecule or hybridoma is readily available to the public and that all restrictions which may have been imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, Applicant's arguments are not persuasive and the rejection is maintained.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 – 2 and 9 – 10 stand rejected, and newly added claims 32 – 33 are rejected, under **35 U.S.C. 102(b)** as being anticipated by Linsley et al. (US Pat. 5,521,288, see entire document) as evidenced by Paul (Fundamental Immunology, 1999, page 451), for the reason of record; and, in response to Applicant's arguments, as further evidenced by Beaudette-Zlatanova et al. (Am J. Tranplant., 2006, 6: 857 – 858).

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that Linsley et al. do not enable methods of downmodulating an autoimmune response in a subject having type I diabetes, because Linsley et al. only demonstrated that an anti-CD28 antibody inhibits in vitro immune responses.

This is not found persuasive, because Linsley et al. explicitly teach that anti-CD28 antibodies can be used to treat insulin-dependent diabetes mellitus (column 36 lines 36 – 43), and it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). Furthermore, the enablement of prior art is evidenced by teachings of e.g. Beaudette-Zlatanova et al. (Am J. Tranplant., 2006, 6: 857 – 858), who observed that two anti-CD28 monoclonal antibodies with different functional activities completely prevented diabetes in BBDP rats (see the Abstract). Given the breadth of the instant claims, which encompass any degree of downmodulation of any type of autoimmune response, the teachings of Linsley et al. are deemed to be anticipatory, as additionally evidenced by Beaudette-Zlatanova et al.

Claims 32 and 33 are included in the rejection, because Linsley et al. teach "inhibition of anti-CD28 mAbs on cognate T_h:B interactions" (column 36, lines 36 – 37),

which inherently involves inhibition (i.e. downmodulation) of CD28-mediated interactions.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

8. Claims 1 – 4, 9 – 12, 28 and 30 stand rejected, and newly added claims 32 – 36 are rejected, under **35 U.S.C. 102(e)** as being anticipated by Yu et al. (US Pat. Pub. 2002/0006403, see entire document) as evidenced by Paul (Fundamental Immunology, 1999, page 451), for the reasons of record; and, in response to Applicant's arguments, as further evidenced by Beaudette-Zlatanova et al. (Am J. Tranplant., 2006, 6: 857 – 858).

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that Yu et al. do not enable methods of downmodulating an autoimmune response in a subject having type I diabetes, because Yu et al. only demonstrated that an anti-CD28 antibody prevents graft-versus-host disease.

This is not found persuasive, because Yu et al. have demonstrated that anti-CD28 antibodies are effective in downmodulating an immune response in vivo (e.g. Example 3 at page 22). Furthermore, Yu et al. explicitly teach that blocking anti-CD28 antibodies can be used to treat autoimmune diseases, such as diabetes mellitus (see Summary of Invention at paragraphs 0010 – 0023, and in particular paragraph 0013), and it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). In

addition, the enablement of prior art is evidenced by teachings of e.g. Beaudette-Zlatanova et al. (Am J. Tranplant., 2006, 6: 857 – 858), who observed that two anti-CD28 monoclonal antibodies with different functional activities completely prevented diabetes in BBDP rats (see the Abstract). Given the breadth of the instant claims, which encompass any degree of downmodulation of any type of autoimmune response, the teachings of Yu et al. are deemed to be anticipatory, as additionally evidenced by Beaudette-Zlatanova et al.

Claims 32 – 36 are included in the rejection, because Yu et al. teach that anti-CD28 antibody functions by preventing CD28/B7 interaction (e.g. paragraph 0021), i.e. by downmodulating a CD28-mediated interaction.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

9. Applicant's reference to the discussion of Ex parte Yu and Anasetti (Appeal No. 2005-1971; BPAI 2006) is acknowledged.

Applicant is reminded that the opinion in support of the decision in Ex parte Yu and Anasetti is not binding precedent of the Board. Further, Applicant has not made of record Applicant's arguments based upon the decision in Ex parte Yu and Anasetti that would be relevant to the prosecution of the instant application.

No further comment by the Examiner is deemed necessary at this time.

10. Conclusion: no claim is allowed.

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.
Patent Examiner
Art Unit 1644

March 2, 2007

PHILLIP GAMBEL, PH.D. J.D.
PRIMARY EXAMINER
TC 1600
3/5/07